

## **REMARKS**

### **Amendments**

By the above amendments, claims 48-50 are cancelled and claims 51-52 are amended to refer to the hydrochloride salt rather than a derivative. These amendments are similar to the Amendments submitted in the April 3, 2002 Reply.

### **Rejection Under 35 U.S.C. §103**

Claims 48-50 were rejected as being obvious in view of Black et al. (US 116) or Dodge et al. (US 417).

This rejection is rendered moot by the cancellation of claims 48-50. Applicants will pursue this subject matter in a divisional application.

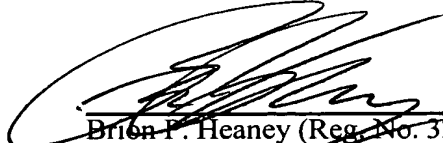
### **Rejection Under 35 U.S.C. §112, first paragraph**

Claims 51-52 were rejected as non-enabled based on the recitation of "derivatives." Applicants' disclosure clearly refers to derivatives of raloxifene. See, e.g., page 6, lines 10-19. Further, applicants' disclosure refers to EP 0 635 270 with regards to a use of raloxifene and derivatives thereof. EP'270 further cites US 4,418,068 as disclosing raloxifene. See the examples of US '068 which describe raloxifene and its hydrochloride salt.

The form of raloxifene that is commonly used is the hydrochloride salt. See, e.g., USP Dictionary of USAN and International Drug Names (2001), p. 746. The USP Dictionary indicates that "Raloxifene" is the INN name for raloxifene hydrochloride. Thus, one of ordinary skill in the art would clearly recognize that applicants' disclosure of raloxifene and derivatives thereof would encompass the hydrochloride salt. See also the disclosure of EP '270 which also describes the hydrochloride salt of raloxifene.

To further prosecution, applicants have amended claims 51 and 52 to refer to the hydrochloride salt of raloxifene. In view of the above remarks, withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

**Please amend claims 51-52 as follows:**

--51. A method for ameliorating LHRH analogue-induced reduction in bone density in a patient comprising administering to said patient one or more LHRH analogues and Raloxifen or the hydrochloride salt thereof ~~a derivative thereof~~ wherein said one or more LHRH analogues and Raloxifen, or the hydrochloride salt thereof ~~a derivative thereof~~, are administered sequentially or simultaneously.

52. A method of inhibiting LHRH analog-induced detrimental side effects due to the administration of an LHRH analog to a patient, wherein said detrimental side effect is reduction in bone density, comprising administering to a patient in need thereof an effective amount of Raloxifen or the hydrochloride salt thereof ~~a derivative thereof~~--